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U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Attention: Privacy-P
Room G-322A
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on the Proposed Standards for Privacy of Individually Identifiable Health Information (RIN 0991-AB08)

Dear Assistant Secretary:

On November 3, 1999, the Department of Health and Human Services (“HHS”) published proposed regulations regarding “Standards for Privacy of Individually Identifiable Health Information.” 64 Fed. Reg. 59918. The American Academy of Ophthalmology (“AAO”) and the Eye Bank Association of America (“EBAA”) welcome the opportunity to comment on these proposed regulations. While we support the goals of protecting privacy we are concerned that, unless modified, the regulations may unintentionally impede the ability of eye transplant agencies to facilitate transplant operations, research, and medical advancements. If the intent of the proposal is to protect current organ and tissue procurement activities, we applaud it. However, we seek further clarification as it relates to eye and eye tissue procurement activities. Important policy considerations support exempting *all* activities related to the procurement and distribution of eyes and eye tissue from the individual authorization requirement. Accordingly, the AAO and EBAA request that HHS clarify the proposed regulations by modifying the definitions of “health care” and “individual” so as to allow essential donor information to be gathered and exchanged by and between certain entities on an expedited basis, as necessitated by the nature of the donation process. We also suggest that HHS maintain (with clarification) the research exception that applies to the use or disclosure of deceased individuals’ protected health information (“PHI”).

I. The Eye Bank Community and the Donation Process

The American Academy of Ophthalmology is the world's largest ophthalmic educational and scientific non-profit organization. The Academy's mission is to

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advance the lifelong learning and professional interests of ophthalmologists to ensure that the public can obtain the best possible eye care. The Academy represents nearly 20,000 eye physicians and surgeons.

Founded in 1961, the EBAA is a non-profit organization dedicated to the restoration of sight through the promotion and advancement of eye banking. EBAA's 108 member eye banks, located worldwide, make possible more than 46,000 sight restoring transplants annually. As the oldest transplantation organization in America, the EBAA has led the field with the establishment of medical standards for the procurement and distribution of eyes and comprehensive certification programs for technicians. These standards and certification programs have served as models for other transplant organizations, as well as state legislation in jurisdictions such as Florida and New York.

AAO member ophthalmologists rely upon EBAA member organizations to obtain the eyes and eye tissue necessary to perform surgery, conduct research, and improve medical education. EBAA provides grants to encourage research advancing the restoration of sight. Thus, the donation and distribution of eyes and eye tissue are integral to the functioning of each organization.

Last year more than 45,000 individuals donated their eyes for purposes of transplantation, research, medical education, and therapy. In 1998, over 47,000 individuals made donations to eye banks. Of these donations, 47,425 eyes were used for corneal grafts and 21,904 for research purposes. Donations are also used for medical education. *Time is the critical factor in procuring and distributing eyes.* The standard of practice among eye banks is to recover donor eyes *within the first six hours* after death to assure viability for transplantation and research. *Slowing down the process risks the loss of viable eye tissues.*

To facilitate donations from individuals who did not authorize donation before death, hospitals and eye banks typically use and/or disclose PHI (as defined at 42 C.F.R. § 164.504¹) without authorization to determine whether the donation is suitable. The process begins upon the imminent or actual death of an individual. At this stage, the hospital will typically contact a transplant organization or its agent to begin the screening process.² At this

¹ For purposes of these comments, we refer to the proposed regulatory provisions by their proposed Code of Federal Regulation designation.

² This system mirrors the Health Care Financing Administration's Condition of Participation regulations ("HCFA's COP regulations"), which require hospitals to notify Organ Procurement Organizations ("OPOs") of every death or imminent death. See 42 C.F.R. Pt. 482. Eye banks are not typically OPOs.

preliminary stage eye banks consider it inappropriate and insensitive to involve grieving families in what may prove to be a futile endeavor. The information needed typically includes: the name of the decedent, the patient identification number, the time and date of death, and a brief health history to evaluate the possibility of infectious diseases (such as HIV or hepatitis).

Thus, an initial determination of suitability is contingent upon access to, and analysis of, the potential donor's PHI provided to the transplant organization by the hospital. Following this determination, the decedent's (or individual facing imminent death's) next of kin is approached for consent to donate for corneal transplantation, eye research and medical education. This consent includes, among other things, an authorization for the release of the donor's medical history.

After obtaining this consent, the eye bank creates a comprehensive donor profile from a variety of sources and assigns a donor number. Based upon the above referenced consent, the eye bank makes the eyes or eye tissue available for transplant, research, or medical education using the assigned donor number. Current Food and Drug Administration regulation requires that eyes or eye tissue be labeled with some PHI for distribution purposes.

Due to the fact that eye banks rely upon the voluntary decisions of individuals and their next of kin to donate, confidentiality is a high priority to ensure public trust and confidence in the system. The EBAA has developed and widely circulated to its members medical and ethical standards that address the need to maintain donor and recipient confidentiality. [Attachment A]

DEFINITIONS

II. AAO and EBAA Are Concerned that the "Definitions" in the Proposed Regulations Inadvertently Hamper the Activities Necessary to Procure and Distribute Eyes and Eye Tissue.

AAO and EBAA are concerned that as currently defined, the definitions of "health care" and "individual" do not encompass all of the activities necessary to carry out the procurement and distribution of eyes and eye tissue.

A. "Health Care"

Under the proposed regulations, no authorization is required for the use or disclosure of PHI in connection with "treatment," "payment" or "health care operations." See 45 C.F.R. § 164.506(a)(1). The regulations define "treatment" as, among other things, "the provision of health care by, or the coordination of health care . . . among health care providers." See *id.* at § 164.504. "Health care" is defined to include any " . . . [p]rocurement or banking of blood,

sperm, organs, or any other tissue for administration to patients.” *See id.* at § 160.103. In addition, uses or disclosures of the PHI of a deceased individual for research purposes appear not to require an authorization. *See id.* at § 164.506(f). All other uses or disclosures of PHI must be pursuant to a valid authorization, except for the uses and disclosures enumerated as exceptions to the general authorization rule. *See id.* at §§ 508 & 510. One such exception is for uses or disclosures “otherwise required by law.” *See id.* at § 510(n). The regulations, however, create several ambiguities that, if left unchanged, could threaten the ability of eye banks to continue their work.

First, it is unclear whether eyes or eye tissue are within the definition of “health care.” In the transplant community, eyes and eye tissue have always been treated as distinct from vascularized organs and other tissues. Because these regulations do not include eyes or eye tissue in the list of biologicals that may be procured without an authorization, it is unclear whether eyes and eye tissue come within the definition. Therefore, HHS should clarify the definition of “health care” by expressly adding “eyes or eye tissues” to the list of biologicals in the definition.

Second, the use of the term “administration to patients” is problematic because it is unclear as to what activities HHS is referring. The definition does not explain this phrase, nor does the preamble. We are concerned that while the definition includes the term “procurement,” it does not appear to include the distribution and screening activities that are central to eye banks. Therefore, we suggest that HHS modify this definition to include these activities as part of “health care.” Accordingly, we suggest the following modification to the definition of “health care:”

***Health care* means the provision of care, services, or supplies to a patient and includes . . . (3) Procurement, processing, screening, distribution, or banking of blood, sperm, organs, eyes or eye tissue, and any other tissue.**

B. “Individual”

The definition of “individual” is similarly vague and threatens the ability of eye banks to obtain authorization from a decedent’s next-of-kin for the use or disclosure of necessary PHI. The current provision defines “individual” to include “an executor, administrator, or other person authorized under applicable law to act on behalf of the decedent’s estate.” These designated persons clearly may authorize the use or disclosure of PHI of a deceased individual. *See id.* at § 164.504(1)(iii). It is less clear, however, whether the next-of-kin could authorize the use or disclosure of PHI, even if he or she is authorized to donate the eye or eye tissue under state law. Indeed, the definition as proposed suggests otherwise. Eye banks seeking to procure, screen, and distribute viable eyes and eye tissue must act quickly. They would lose valuable time trying to determine whether an individual is designated to act on the behalf of the decedent’s estate. In addition, eye banks are not

equipped to make such determinations. The proposed regulations add a level of complexity and complication that could seriously impede the recovery of viable eyes and eye tissue in a timely manner.

Therefore, we suggest that HHS modify the definition of "individual" in the following manner so as to permit the next-of-kin, if available, to authorize uses or disclosures of PHI related to the eye and eye tissue donation process:

***Individual* means the person who is the subject of the protected health information, except that: (1) "Individual" includes: . . . (iii) With respect to deceased persons, the next-of-kin (as defined under applicable law) or an executor, administrator, or other person authorized under applicable law to act on behalf of the decedent's estate.**

The eye bank community requests these modifications to the definitions to ensure that the proposed regulations do not impede the uses and disclosures that are a necessary part of the flow of information between entities engaged in the procurement and distribution of eyes and eye tissue.

DECEASED PERSONS

III. AAO and EBAA Strongly Support the Research Exception to the Two-Year Period of Confidentiality for the Use and Disclosure of a Deceased Individuals' PHI

The proposed regulations establish the general rule that an individual's PHI remains confidential for two years after that individual's death. The only exception appears to be that the PHI of a deceased individual may be used or disclosed for research purposes without an authorization after death. *See id.* at § 164.506(f). Thus, under this provision, PHI obtained from a deceased individual could be used or disclosed for research purposes without an authorization and without the approval of an Institutional Review Board ("IRB"). AAO and EBAA applaud HHS's recognition of the need for such an exception, but request confirmation that PHI obtained *during the donation process* of eyes and eye tissue can be used or disclosed for research purposes without an individual authorization and without the approval of an IRB.

Research is essential to improving the diagnosis and treatment of diseases and disorders of the eye. When eyes or eye tissue have been donated but are unsuitable for transplantation, the eye tissue is placed with academic teaching hospitals, research facilities and individual ophthalmologists to advance understanding of eye and vision disorders. When notified of a potential donation, an eye bank will use PHI to screen the donation. Requiring an authorization at the screening stage would add a cumbersome step to the

process since eye banks do not then know if eyes or eye tissue will be used for transplantation or research. Such a requirement would impede the efforts of eye banks to facilitate important research.

Secondly, subjecting these initial uses or disclosures of PHI for screening purposes to IRB approval, which can take several weeks, would similarly severely hamper the provision of eyes and eye tissue to the researchers. Unlike the researchers who eventually obtain the eyes or eye tissue, eye banks need to use and disclose the PHI during the initial procurement, processing, screening, and distribution process. As noted, this process is extremely time sensitive. In most cases, there are only six hours in which an eye bank can act and maintain the viability of the eyes or eye tissue.

Therefore, AAO and EBAA suggest that HHS maintain the research exception for the use or disclosure of a deceased individual's PHI after death and clarify that this information may be used or disclosed to or by eye banks for research purposes.

IV. Conclusion

AAO and EBAA believe the definitions of "health care" and "individual" should be modified so as to include all activities directly related to the donation process. We also believe the proposed research exception to the post-death two-year period of confidentiality be maintained and clarified to ensure that eye banks can use this information during the donation process for research purposes. We place great importance on maintaining the confidentiality of patient information, but stress that the flow of PHI is absolutely essential for facilitating transplant operations, research, therapy, and the advancement of medical education.

We appreciate the opportunity to share our concerns with HHS.

Respectfully submitted,



William L. Rich III, MD
Secretary for Federal Affairs
American Academy of Ophthalmology
1101 Vermont Avenue, NW, Suite 700
Washington, DC 20005-3570
202-737-6662



Patricia Aiken-O'Neill, Esq.
President/CEO
The Eye Bank Association of America
1015 18th St., NW Suite 1010
Washington, DC 20036
202-775-4999

Attachment A



Medical Standards

**These Standards have the approval of the Eye Banking Committee
of the American Academy of Ophthalmology**

November 1999

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EBAA MEDICAL STANDARDS

A1.000 Introduction and Purpose

These standards have been developed to assure consistently acceptable levels of quality, proficiency, and ethics in dealing with eye tissue for transplantation and define the minimum standards of practice in the procurement, preservation, storage, and distribution of eye tissue for transplantation and research, as determined by the ophthalmological medical community.

A1.100 Scope

These standards are intended to apply to any and all aspects of eye banking, to include:

- Identification and screening of donors
- Procurement of eye and corneal tissue
- Laboratory processing of tissue, including preservation and biomicroscopic examination of tissue
- Storage of tissue
- Distribution of tissue for transplantation, research and teaching

These standards shall be reviewed at least annually and revised as necessary to incorporate current research findings and improved clinical practice.

B1.000 Accreditation

In order for an eye bank to become an accredited member of the Eye Bank Association of America, it must comply with the EBAA Bylaws and the following:

1. Demonstrate compliance with EBAA Medical Standards.
2. Pass the site inspection by the EBAA Medical Standards Committee.
3. Demonstrate proficiency in all aspects of eye banking by procuring, processing and distributing (within the geographic territory it defines as its service area) at least 25 surgical corneas for penetrating keratoplasty annually and provide documentation of their performance.
4. Certify compliance with applicable Federal and State regulations.

Eye Banks applying for EBAA membership must complete the Medical Advisory Board Questionnaire. Pending approval of the EBAA Board of Directors, the applicant may be accepted for provisional EBAA membership and will be subject to an on-site inspection within one year. A provisional member eye bank must complete the accreditation process within one year after obtaining provisional status in the EBAA. Any provisional member eye bank failing to complete the accreditation process after a site inspection will have until the time of the next meeting to correct deficiencies and satisfy accreditation

requirements. If, at the end of this period, the provisional member eye bank fails to meet accreditation standards, it may not proceed to full membership with voting rights.

Once accredited, an eye bank must be inspected and reaccredited at least every three years to maintain accreditation and voting membership in the EBAA.

B1.100 Eye Bank Inspection

The Accreditation Committee of the EBAA shall be responsible for inspecting member Eye Banks as outlined in the written procedures of the Committee.

Accreditation and reaccreditation site inspections shall be scheduled following written notification of the impending inspection. Unannounced inspections may be conducted should an allegation of violation of Medical Standards be made to the committee, or should the results of inspections by official agencies indicate violation of Medical Standards. A copy of the written report of the results of the inspection shall be sent to the Chair of the Accreditation Committee within ten (10) working days of the receipt. The Accreditation Committee shall be copied on all future correspondence relating to the inspection. Failure to permit an inspection will result in suspension or revocation of an eye bank's accreditation.

Demonstration of proficiency in any and all aspects of eye banking may be required during the site inspection and of any or all technical personnel.

C1.000 Personnel and Governance

C1.100 Director

All policies and procedures of each eye bank shall be under the supervision of a Director appointed by the eye bank's Board of Directors, Board of Regents or other governing body. The Director shall be responsible for all administrative operations including compliance with these standards.

The Director shall be the individual responsible for the day-to-day operation of the Eye Bank. It is this individual's responsibility to carry out policies of the Eye Bank's Board, to determine what tissues are to be collected, and to prescribe clinically acceptable means for their processing, quality control, storage and distribution.

The Director, if not a physician, shall consult with the Medical Director, as well as other medical and legal authorities, in carrying out prescribed responsibilities as necessary. These consultations shall be documented and made available for review during a site inspection.

The Director shall provide all staff members with adequate information to perform their duties safely and competently. Delegation of responsibility for the clinical work of the eye bank shall be as follows:

C1.200 Medical Director

The Eye Bank must have a Medical Director. When the Medical Director is not available, a back-up Medical Director shall be designated who is capable of fulfilling the responsibilities of the Medical Director on an interim basis.

The Medical Director must be an ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research or teaching in cornea and/or external disease. If the Medical Director has not served a corneal fellowship, then the eye bank must have and document a consulting relationship with an ophthalmologist who has.

Each Medical Director and co-directors of each member eye bank shall attend the Medical Directors' Symposium at the annual meeting of the EBAA at least once every three years and a Medical Advisory Board meeting once every three years. A newly appointed Medical Director shall attend a Medical Directors' Symposium within one year of appointment, unless a Co-Medical Director has fulfilled the requirement. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

The Medical Director shall oversee and provide advice on all medical aspects of the Eye Bank operations. These include but are not limited to:

1. Formulation, approval, and implementation of medical policies and procedures.
2. Participation in training and oversight of technical staff with regard to tissue procurement, tissue preservation and tissue evaluation.
3. Participation in establishment and operation of a quality assurance program.
4. Responsibility for verification of competency for tissue procurement and preservation by personnel applying for CEBT certification.

The Medical Director may delegate responsibility for tissue procurement, preservation, and tissue evaluation to qualified eye bank personnel; however, the Medical Director shall ensure that the eye bank operates in compliance with the EBAA Medical Standards. Ultimate responsibility for the suitability of each tissue for the transplantation in patients rests with the transplanting eye surgeon.

An eye bank has three months to replace a Medical Director who has resigned.

C1.300 Technical Staff

The Director shall appoint technical staff and ensure that staff has the appropriate qualifications and training for the performance of their job responsibilities. The Director shall ensure that there are a sufficient number of qualified eye bank technicians and supportive technical staff to promptly and proficiently perform all eye bank laboratory tests and procedures.

Each eye bank must have at least one EBAA certified technician in a supervisory role. If the medical director fulfills this role, he or she must pass an EBAA Technician Certification exam and maintain that certification. For non-certified technicians, the eye bank Executive Director or Medical Director must designate in writing those nonphysician technicians who are qualified and authorized to perform eye bank laboratory procedures.

An eye bank has six months in which to replace the EBAA certified eye bank technician in a supervisory role. The EBAA office and the Chair of the Accreditation Committee shall be notified in writing of the lack of an EBAA certified technician in a supervisory position. If a six month deadline cannot be met, an extension can be granted under the following circumstances: a) the eye bank submits appropriate evidence of its intent to comply with this standard, b) a consulting relationship is established with the Technical Director (CEBT) of an accredited eye bank, and c) the non-CEBT technician in charge in the interim has demonstrated satisfactory proficiency to a member of the EBAA Practical Performance Committee.

C1.400 Change in Governance

An eye bank that undergoes a change in governance must notify the EBAA office and the Chair of the Accreditation Committee (in writing) within 30 days. Changes in governance include merger of eye banks, affiliation of two or more eye banks, affiliation of an eye bank with another non-eye bank organization (E.G. tissue banks, organ procurement organizations, hospitals, blood banks, etc.), a change in the name of the eye bank, or a change in required personnel, i.e. Director, Medical Director.

C2.000 Training, Certification, and Continuing Education of Technical Personnel

An eye bank must provide an orientation program for each new technician and the employee's participation must be documented.

An eye bank must provide educational opportunities such as in-service training programs, attendance at meetings, seminars, and workshops for all technical personnel, including laboratory supervisors, at a frequency that is defined and reasonable for the size and needs of the technical staff.

For an eye bank technician to receive EBAA Certification, he or she must pass the EBAA Technician Certification examination. To sit for the examination, the eye bank technician must be employed by a transplant organization and be recommended by the Executive Director or a physician meeting the requirements of a medical director, as outlined in Section C1.200. A passing grade in both the written and practical portions of the exam will result in EBAA certification, provided that the appropriate fees have been paid. An EBAA certified technician must renew his or her certification at least once every three years by documenting the specified minimum number of continuing education units (CEU's) which have been approved by the EBAA Technician Subcommittee. To maintain certification, a technician must attend an EBAA meeting at least once every three years.

All EBAA accredited eye banks must have one Certified Eye Bank Technician (CEBT) attend an EBAA sponsored skills workshop once every three years. Each eye bank shall institute and document an in-house technician skills review and training for all technical staff on an annual basis.

C3.000 Facilities

Each eye bank must have sufficient space, equipment and supplies to perform the volume of laboratory services with optimal accuracy, efficiency, sterility, timeliness and safety. The EBAA office and the Chair of the Accreditation Committee shall be notified of the relocation of an eye bank.

C3.100 Eye Bank Laboratory

The laboratory must be a separate area with limited access in which activities directly related to eye banking are carried out. The laboratory shall have a sink with a drain and running water. There must be adequate counter space for preparation of donor material. The room including walls, flood and sink must be kept clean at all times. Appropriate documentation of regular laboratory cleaning schedules must be maintained and kept on file for a minimum of three years.

Each eye bank laboratory must have an adequate stable electrical source and a sufficient number of grounded outlets for operating laboratory equipment.

C3.200 Equipment, Maintenance and Cleaning

Each eye bank laboratory shall have a refrigerator with a device, visible without opening the refrigerator, for recording temperature variations. Temperature variations must be recorded daily and remain within the range of 2 to 6° Celsius. These records must be kept for a minimum of three years. The refrigerator's continuous temperature recorder must be calibrated against an NIST standard thermometer at least once a year. The refrigerator shall be maintained for the

use of tissue and tissue storage media and must contain clearly defined and labeled areas for all tissue stored, i.e., quarantined tissue, surgical tissue awaiting distribution, and research tissue.

A laminar airflow cabinet or hood, is required for the preservation of any ocular tissue in the laboratory.

In the event of a power failure, there must be provision for immediate notification and action to be taken, which may include an emergency power supply to maintain essential refrigeration.

Appropriate maintenance and accreditation records must be maintained on each piece of equipment. These records must show dates of inspection, performance evaluations and any maintenance procedures or repairs performed. These records must be kept at least three years.

The eye bank must include in its procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of equipment. Documented cleaning schedules for laboratory equipment must be kept on file for a minimum of three years.

C3.300 Instruments and Reagents

Adequate instrumentation must be available to provide for sterile removal of whole eyes and corneas. Instruments must be inspected frequently enough to assure that they function properly. An eye bank that uses autoclave to sterilize its instruments shall adhere to the maintenance procedures for autoclaves in the Procedures Manual, (Section C3.200) or if instruments are sterilized outside of the eye bank, the eye bank shall provide documentation of appropriate sterilization.

All sterilized instruments, supplies and reagents, such as corneal preservation medium, must contain sterilization dates, method or appropriate expiration dates that are current at all times if applicable.

C3.400 Procedures Manual

Each eye bank shall maintain its own procedures manual that details all aspects of its specific retrieval, processing, testing, storage, distribution, and quality assurance practices. Each procedure must be initially approved, signed, and dated by the Director and Medical Director. An annual review of each eye bank's procedure with signing and dating by the Director and Medical Director is required. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use.

C3.500 Satellite Laboratories

Satellite laboratories that either process or distribute tissue must have a certified technician and be supervised by and have access to a qualified Medical Director or his/her delegate. Such satellite laboratories must be inspected as part of the accreditation process of the parent bank.

C3.600 Infection Control and Safety

Written safety procedures for the eye bank operation shall be established in compliance with the Occupational Safety and Health Act (OSHA Act) of 1970 and the 1991 amendments to Part 1910 of title 29 of the Code of Federal Regulations, Subpart Z and/or applicable state statutes, which may supersede. All eye bank personnel must operate under the current Universal Precautions for health care workers issued by the Centers for Disease Control (CDC) of HHS.¹ These written procedures must be included in the eye bank's procedure manual.

C3.700 Waste Disposal

Human tissue and waste items shall be disposed of in such a manner as to minimize any hazard to Eye Bank personnel and the environment and to comply with state and federal regulations. Dignified and proper disposal procedures shall be used to obviate recognizable human remains and must be documented.

D1.000 Donor Screening

All donors must be identified by name. All prospective donors shall undergo a thorough physical examination as close as possible prior to donation with special attention to physical signs of HIV disease, infectious hepatitis, and injecting drug use. Each eye bank shall have a consistent policy for conducting and documenting this examination. Each eye bank shall also have a consistent policy for examination and documentation of the prospective donor's available medical record and death investigation. Review of all available records on each donor shall be performed by an individual who is qualified by profession, education, or training to do so, and who is familiar with the intended use of the tissue.

Medical and social history are important aspects of donor evaluation. Adequate donor evaluation includes:

- (1) serologic testing (see Section G1.200)
- (2) physical assessment of the donor (see above paragraph)
- (3) tissue evaluation (see F1.000)

¹ On December 6, 1991, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor (DOL) published its final rules regulating worker occupational exposure to bloodborne pathogens, including but not limited to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). These regulations went into effect March 6, 1992, and make employers responsible for providing and ensuring safe working conditions in all work settings. See the December 6, 1991, *Federal Register*, Vol. 56, no. 235.

- (4) donor history evaluation: this must include the donor's name and donor information obtained from at least one of the following:
- a) pathologist or medical examiner physical assessment of death report
 - b) police investigation report (accompanied by a and/or c)
 - c) medical examiner's investigative report
 - d) family interview
 - e) medical record or hospital chart
 - f) treating physician interview
- (5) medical director oversight to review any donor information where questions arise in the above areas (C1.200). This shall be documented.
- (6) Information shall be sought for available sources to rule out the possibility of CJD and other related diseases, specifically evaluating (a) change in cognition, (b) Cerebellar dysfunction, (c) speech abnormalities, (d) upper motor neuron signs such as myoclonus. This standard shall not be implemented until further data is obtained from a newly formed subcommittee using outside experts in the field of Prion disease.

D1.100 Screening of Donors Must be Conducted for the Following:

D1.110 Tissue from donors with the following is potentially hazardous to eye bank personnel and requires special handling:

- Active Viral Hepatitis
- Acquired Immunodeficiency Syndrome (AIDS) or HIV seropositivity
- Active viral encephalitis or encephalitis of unknown origin
- Creutzfeldt-Jacob Disease
- Rabies

D1.120 Contraindications

Tissue from donors with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes:

A. Penetrating Keratoplasty

1. Death of unknown cause
2. Death with neurologic disease of unestablished diagnosis
3. Creutzfeldt-Jacob disease and family history of a blood relative with Creutzfeldt-Jacob disease
4. Subacute sclerosing panencephalitis
5. Progressive multifocal leukoencephalopathy
6. Congenital rubella
7. Reyes Syndrome

8. Active viral encephalitis or encephalitis of unknown origin or progressive encephalopathy
9. Active septicemia (bacteremia, fungemia, viremia)
10. Active bacterial or fungal endocarditis
11. Active viral hepatitis
12. Rabies
13. Intrinsic eye disease
 - a. Retinoblastoma
 - b. Malignant tumors of the anterior ocular segment or known adenocarcinoma in the eye of primary or metastatic origin
 - c. Active ocular or intraocular inflammation: conjunctivitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis
 - d. Congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus
 - e. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button
14. Prior intraocular or anterior segment surgery
 - a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.
 - b. Laser photoablation surgery
 - c. Corneas from patients with anterior segment (e.g., cataract, intraocular lens, glaucoma filtration surgery) may be used if screened by specular microscopy and meet the Eye Bank's endothelial standards.
 - d. Laser surgical procedures such as argon laser trabeculoplasty, retinal and panretinal photocoagulation do not necessarily preclude use for penetrating keratoplasty but should be cleared by the medical director.
15. Leukemias
16. Active disseminated lymphomas
17. Hepatitis B surface antigen positive donors (as specified in Section G1.230)

18. Recipients of human pituitary-derived growth hormone (pit-hGH) during the years from 1963-1985²
19. HTLV-I or HTLV-II infection
20. Recipient of Dura Mater graft
21. Hepatitis C Seropositive donors
22. HIV Seropositive donors (as specified in Section G1.220)
23. HIV or high risk for HIV: Persons meeting any of the following criteria should be excluded from donation:

Behavioral/History Exclusionary Criteria: (May, 1994 CDC Guidelines)

- a. Men who have sex with another man in the preceding 5 years.
- b. Persons who reported nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.
- c. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates.
- d. Men and women who have engaged in sex for money or drugs in the preceding 5 years.
- e. Persons who have had sex in the preceding 12 months with any person described in items a-d above or with a person known or suspected to have HIV infection.
- f. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane.
- g. Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population.)

Specific Exclusionary Criteria for Pediatric Doctors:

- h. Children meeting any of the exclusionary criteria listed above for adults should not be listed as donors.
- i. Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors (regardless of their HIV status) should not be accepted as donors unless HIV infection can be excluded in the child as follows:

² Potential donors who received pituitary-derived growth hormone (pit-hGH) during childhood at any time during the years from 1963-1985 should not be accepted as eye or corneal donors because of potential risk of transmitting Creutzfeldt-Jacob disease (CJD). Some 7,000 U.S. children received therapeutic pit-hGH through early 1985 and there are unknown numbers of persons who may have used this drug non-therapeutically, e.g., during rigorous physical training. All known recipients and their treating endocrinologists have been notified and a fact sheet is available, HHH Publication No. 88-2793, December 1987.

Children >18 months of age who are born to mothers with or at risk for HIV infection, who have not been breast fed within the last 12 months, and whose HIV antibody tests, physical examination, and review of medical records do not indicate evidence of infection can be accepted as donors.

- j. Children ≤18 months of age who are born to mothers with or at risk for HIV infection or children of mothers with or at risk of HIV infection who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV tests results.

Laboratory and Other Medical Exclusionary Criteria:

- k. Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g. hemodilution that could result in false-negative tests), or any other reason.
- l. Persons with repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of the supplemental assays.
- m. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting >1 month, unexplained temperature >100.5 F (38.6 C) for >10 days, unexplained persistent diarrhea, male-to-male sexual contact, a history of syphilis or gonorrhea within the previous 12 months, or needle tracks or other signs of parenteral drug abuse.

B. Lamellar or Patch Grafts

Criteria are the same as listed for penetrating keratoplasty except that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma, e.g., aphakia, iritis, is acceptable for use.

C. Epikeratoplasty

Criteria are the same as listed for penetrating keratoplasty except that tissue with local eye disease affecting the corneal endothelium, e.g., aphakia, iritis, is acceptable for use. Death to preservation time may be extended.

D. Scleral Tissue

Criteria are the same as listed for penetrating keratoplasty except that tissue with local eye disease affecting the corneal endothelium, e.g., aphakia, iritis, is acceptable for use. Death to preservation time may be extended.

D1.200 Documentation on Donor Information

Donor screening forms and/or copies of medical charts, medical examiner or coroner review forms and gross autopsy results must be completed and retained on all donated eye tissue as part of the donor record. *See Section 11.000.*

A unique donor identifying number, i.e, medical examiner or coroner case number, hospital medical record number, social security or driver's license number, shall be obtained and recorded in the donor record.

D1.300 Method of Consent

Documentation of legal consent for enucleation or in situ excision is essential for medical-legal reasons. Consent procedures and forms must conform with state law and documentation for consent must be retained. In medical examiner's/coroner's cases, the eye bank shall adhere to the consent regulations specified by the medical examiner's or coroner's legislation in its state. In each case the consent designation and restrictions, if any, must be adhered to and cannot be altered without the witnessed resigning or redesignation of the legally appropriate consentor.

D1.400 Donor Age

Since no definite relationship has been established between the quality of donor tissue and age, the upper and lower age limit is left to the discretion of the Medical Director.

D1.500 Interval Between Death, Enucleation, Excision and Preservation

Acceptable time intervals from death, enucleation or excision to preservation may vary according to the circumstances of death and interim means of storage of the body. It is generally recommended that corneal preservation occur as soon as possible after death. All time intervals for each donor, i.e., the time of death to the time of enucleation and preservation and/or the time to corneal excision, shall be recorded. If the donor has been refrigerated prior to enucleation or in situ corneal excision, this information shall be noted.

D1.600 Eye Maintenance Prior to Enucleation

The prospective donor's corneal integrity should be maintained. Recommended procedures for eye maintenance shall be found in the procedures manual. Each individual eye bank's procedure is left to the discretion of the Medical Director and shall be clearly documented.

D1.700 Living Donors

Eye tissue that is removed and processed for surgical use from a living donor shall have the same standards applied as for all cadaveric tissue, e.g., the same donor medical history shall be obtained, the same records, serology, etc. No extended quarantine period, outside the usual 24-48 hours for serology results, shall be required for corneal tissue used for transplantation that is stored in short or immediate term culture medium.

E1.000 Procurement and Preservation Procedures

Specific procurement procedures can be found in the EBAA Procedures Manual. Variations of these procedures are at the discretion of the eye bank's Medical Director as long as they do not violate standard aseptic practice and are documented. This manual has been approved by the Medical Policy and the Technician's Subcommittees, and shall be periodically reviewed and modified as necessary.

The Medical Director and Director are responsible for assuring that eye bank personnel comply with all applicable procedures for the procurement and preservation of tissue.

E1.100 Enucleation Procedure

Ultimate responsibility for personnel to perform enucleation rests with the Director, the Medical Director and existing state law.

E1.200 In Situ and Laboratory Removal of Corneoscleral Rim

Removal of the corneoscleral rim shall be performed using sterile technique by individuals specifically trained in in situ retrieval and/or laboratory removal of the corneoscleral segment. Laboratory removal must be performed with a laminar air flow hood or cabinet which meets either Federal Standard 209(b) as a Class 100 Hood or National Sanitation Foundation (NSF) Standards as a Class II or Class III cabinet, or in an operating room. For in situ corneal removal, the eye shall be examined with the use of a penlight prior to excision.

E1.300 Use of Short or Immediate Term Preservation Medium

Eye Banks shall use an appropriate corneal storage medium that has been manufactured in accordance with FDA Good Manufacturing Practices. The

medium shall be used and stored according to the manufacturer's recommendations for temperature, date and other factors. The manufactured medium purchased and shipped to the eye bank shall be inspected for damage upon arrival. The lot number of medium used for each cornea shall be recorded on the tissue report containing the unique I.D. number of the tissue to allow tracking and recall.

E1.400 Long Term Preservation

Some eye banks employ long-term preservation of corneal tissue, such as organ culturing. While these methods are not in widespread use, an eye bank that uses long-term preservation shall carefully document the procedure in their procedures manual, and adhere to rigid aseptic technique.

E1.500 Whole Globe Preservation

Procedures for whole globe preservation may be found in the EBAA Procedures Manual. Eye banks that store whole eyes for lamellar or refractive keratoplasty shall employ aseptic practice using one of the preservation methods given in the procedures manual. The selected preservation method must be documented in the eye bank's own procedures manual.

E1.600 Scleral Preservation

Various methods of preserving sclera may be found in the EBAA Procedures Manual. Eye banks shall preserve sclera tissue aseptically, using one of these methods. The selected preservation method must be documented in the eye bank's own procedures manual. A preservation date for scleral tissue shall be indicated.

F1.000 Tissue Evaluation

The ultimate responsibility for determining the suitability of the tissue for transplantation rests with the transplanting surgeon.

F1.100 Gross Examination

The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination and scleral color, e.g., jaundice.

F1.200 Slit-lamp Examination

The cornea shall be examined for epithelial and stromal pathology and in particular endothelial disease. Enucleated whole globes shall be examined in the laboratory prior to distribution and/or corneal excision. If in situ corneal

excision is performed, examination of the donor eye anterior segment with a penlight or a portable slit lamp is required. After corneal excision, the corneal-scleral rim shall be evaluated by slit lamp biomicroscopy, even if the eye donor has been examined with the slit lamp prior to excision of the corneal-scleral rim, to insure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.

The minimum information that must be documented with the slit lamp biomicroscopy is outlined in the EBAA Procedures Manual.

F1.300 Specular Microscopy

Specular microscopy may provide additional useful information in screening donor corneal tissue to determine suitability for transplantation. If the eye bank utilizes specular microscopy, it must have a written procedure that includes how information is used.

G1.000 Quality Assurance

Each eye bank shall have a formally established quality assurance program. This program shall include ongoing monitoring and evaluation of activities, identification of problems, and development of plans for corrective actions. These standards shall provide the basis for development of the QA program. Each eye bank shall document all aspects of its QA program and maintain records of all QA activities for a minimum of ten years. These include any corrective or remedial action taken for detected deficiencies. These records shall be available for review at the time of site inspection.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the source eye bank which in turn, must forward the adverse reaction information within a reasonable time to the EBAA office for review by the Medical Advisory Board. If systemic infectious disease such as HIV, hepatitis, or syphilis develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA. An Adverse Reaction file shall be available for review by the site inspectors at the time of inspection and must be kept for a minimum of ten years. Serious adverse reactions shall be reported immediately to the EBAA office for review by the Medical Advisory Board. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

G1.100 Quality Control

The Director shall prescribe tests and procedures for measuring, assaying or monitoring properties of tissues essential to the evaluation of their safety for transplantation, e.g., hepatitis B surface antigen and human

immunodeficiency virus (HIV) antibody, and conform with federal requirements as well as individual state laws. Results of all such tests or procedures, together with evaluations based on these findings, shall become part of permanent record of all tissues processed.

G1.200 Testing

If an eye bank performs its own microbiologic or serologic testing, it must meet applicable accreditation requirements established under the Clinical Laboratories Improvement Act (CLIA). Verification of satisfactory compliance with a College of American Pathologists (CAP) Proficiency Testing Program, or other proficiency testing program approved by CLIA, shall be available at the time of the site inspection.

G1.210 Microbiologic Culturing

Culturing of Eye Bank donor eyes is advised despite the recognition by many that bacteriologic contamination of donor eyes does not necessarily lead to infection and that presurgical or surgical cultures may not correlate with postoperative infection if it should occur. Cultures may be performed either before and/or at the time of surgery.

A. Presurgical Cultures

Eye Banks may elect to perform corneal-scleral rim cultures at the time of corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.

B. Surgical Culturing

Each eye bank shall recommend culturing of the corneal-scleral rim for corneal transplantation, or a piece of sclera for scleral implantation at the time of surgery. Positive results in cases of postoperative infection shall be reported to the eye bank that procured the tissue as well as to the eye bank that distributed the tissue.

G1.220 Serologic Testing

Sections G1.230-G1.270 specify the EBAA required serologic tests which must be performed on each donor from which tissue is designated for surgical use.

Plasma Dilution Donor Evaluation: Each eye bank shall document on each transplant donor whether blood loss was known or suspected as determined by the Medical Director or qualified designee and whether the donor received any infusion/transfusion of crystalloids and/or colloids and blood. An algorithm meeting FDA regulations shall be used to record

infusion/transfusion volumes given to each donor within 48 hours prior to obtaining the blood sample for serologic testing on every donor with blood loss, and on every donor age 12 and under receiving any amount of infusion/transfusion preceding sampling. If the total volume infused/transfused is equal to or in excess of the donor's total blood volume or plasma volume, the sample is not suitable for testing.

Autologous blood and autologous blood product infusion is excluded from calculations.

G1.230 HIV Screening

All member eye banks must have operational an HIV-1/HIV-2 screening program using an FDA approved test for all donors of surgically designated tissue. To comply with FDA requirements, a negative screening test must be documented prior to release of tissue for transplantation.

G1.240 Hepatitis B Screening

All member eye banks must have an operational hepatitis B screening program using an FDA approved test for hepatitis B surface antigen for all donors of surgically designated tissue. To comply with FDA requirements, a negative screening test must be documented prior to the release of tissue for transplantation.³

G1.250 Hepatitis C Screening

All member eye banks must have an operational Hepatitis C screening program using an FDA approved test for all donors of surgically designated tissue. To comply with FDA requirements, a negative screening test must be documented prior to release of tissue transplantation.

G1.260 HTLV-I and HTLV-II Screening

Donor screening for HTLV-I and HTLV-II is not required.

G1.270 Syphilis Screening

Serologic screening for syphilis is not required.

G1.280 Non-Required Laboratory Results

If laboratory results of non-required tests for infectious disease are reported for tissue for transplantation to the eye bank, they must be taken into account and/or acted upon by the medical director.

³ The EBAA recognizes the use of neutralization assay or confirmatory tests as scientifically valid.

G1.290 Discordant Test Results

All member eye banks must report conflicting serologic test results. In addition, results of other serologic tests that are not required but may be indicative of risk for HIV or hepatitis must also be reported within 60 days.

H1.000 Non-Surgical Donor Tissue

If donor tissue is provided for purposes other than surgery, e.g., research, practice surgery, etc., and if that donor tissue is not screened for HIV or Hepatitis, a label stating that screening for HIV-antibody, Hepatitis B or Hepatitis C has not been carried out or stating "potentially hazardous biologic material" or some other designation acceptable under the guidelines of the CDC must be attached to the container used for the donor tissue storage and/or transport.

I1.000 Storage

All surgical tissue shall be stored in quarantine until results of HIV, HBsAg, HCV, and any other relevant donor screening tests have been recorded as non-reactive.

All tissue shall be stored aseptically at a temperature appropriate to the method of preservation used. Eye banks must precisely document their procedures for storage of corneal tissue, whether it is in the form of the whole eye or the cornea only in an appropriate medium.

J1.000 Labeling

Each corneal or scleral tissue container shall be clearly and indelibly labeled to include at least the information below.

1. Name of source eye bank.
2. Tissue identification number. *There must be a unique identification number for each ocular tissue or fraction thereof that is distributed for surgical use.*
3. Type of tissue.
4. Date and time of donor's death.
5. Date and time of corneal/scleral preservation.
6. Preservation date for scleral tissue and long-term preserved tissue.
7. A statement that the tissue is intended for single patient application only and that it is not to be considered sterile and that the FDA therefore recommends culturing or reculturing.
8. A statement that the tissue was procured from a donor who was non-reactive when tested for HIV antibody, hepatitis B surface antigen (HBsAg), and hepatitis C antibody (HCV).
9. Type of preservation medium.

K1.000 Distribution of Tissue

K1.100 Review of Donor Medical History

Prior to distribution of tissue for transplantation, the Medical Director or his/her designee shall review and document that the medical and laboratory information is in accordance with medical standards.

K1.200 Receivers of Tissue

Tissue shall be distributed to physicians, dentists, institutions and other eye banks.

All tissue sent from EBAA accredited eye banks to eye banks in this or other countries must comply with the standards defined by the EBAA Medical Advisory Board.

K1.300 Fair and Equitable System

Eye banks shall establish and document a system of distribution that is just, equitable and fair to all patients served by the eye bank. Documentation of distribution (time and date of requests for, offers of, and delivery of eye tissue) shall be available for inspection by the Accreditation Committee. Access to tissue shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin.

K1.400 Returned Tissue

For corneas returned and redistributed, tissue transportation and storage information must be documented and made available to the eye bank and transplanting surgeon.

K1.500 Tissue Recall

Eye banks must have a policy and procedure for potential recall of tissue.

L1.000 Documentation to Accompany Donor Tissue

L1.100 Tissue Report Form

For special research studies, by recommendation of the Medical Advisory Board and approved by the EBAA Board of Directors, certain specific data may be masked on the tissue report form and label. A copy of the

tissue report form and/or donor screening form shall accompany the tissue.
The tissue report shall contain the following:

Name of (Source) Eye Bank

Location of Eye Bank

Telephone Number of Eye Bank

Eye Bank identification number unique to each tissue graft

Type of preservation medium

Age of donor

Cause of death

Death date and time

Preservation date and time

Name of technician who enucleated, excised, and evaluated the tissue

Slit lamp report/date

Specular microscopy report/date

EBAA Accreditation Status of Eye Bank

For a medical examiner tissue procured under legislative consent, a statement shall be added to advise the receiving surgeon that the tissue was determined to be suitable for transplantation in the absence of a donor medical history interview.

A summary of records reviewed regarding the suitability of tissue for transplant as described in the FDA Final rule 1270.33(d).

L1.200 Package Insert Form

A "Package Insert" form that meets the EBAA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

1. Recommended storage temperature for specific type of tissue (cornea; sclera; whole globe). Specific emphasis on DO NOT FREEZE for corneas.
2. That the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.
3. For corneas in Optisol. That color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
4. Whether pre-surgical microbiologic cultures were performed by the eye bank, including the advisement that cultures of the donor rim and sclera should be performed at the time of surgery.
5. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.
6. Serologic tests were performed by a laboratory which was approved by CLIA or CAP.

7. The U.S. Food and Drug Administration (FDA) approved tests used for serology are approved for pre-mortem blood samples but have not been validated for cadaveric blood.

This information may be included on the eye bank's donor screening form as long as it is easily noticed; otherwise a separate package insert form is advised.

L2.000 Packaging, Sealing and Packing for Transport

Each tissue shall be individually packaged and sealed with a tamper-evident seal.

The tissue shall be packed in a water-proof container with wet ice, so as to maintain the temperature of the tissue at an acceptable level. Packing shall be done so that the package insert and tissue label do not become wet. Special instructions shall be included on a Package Insert. See *Section L1.200*.

M1.000 Eye Bank Records

M1.100 Length of Storage

All records shall be kept for a minimum of ten years from the date of transplantation/implantation, distribution or whichever is longer.

M1.200 Confidentiality

All eye bank records and communications between the eye bank and its donors and recipients shall be regarded as confidential and privileged.

M1.300 Donor Screening Forms

Donor screening forms shall contain information regarding the circumstances surrounding the death of a donor and adequate medical history so that the suitability of the tissue for transplantation may be judged.

M1.400 Minimum Information to be Retained

Forms for retaining donor and recipient information shall be established for permanent record and shall be readily accessible for inspection by the EBAA Accreditation Committee. Eye Bank records shall include the following minimum information:

See Section L1.000 for information to be included on the Tissue Report Form.

Eye bank identification number unique to each tissue graft

Name of eye bank
Type of preservation medium
Preservation media lot numbers
Unique donor identification number
Name of donor (or if import tissue, name of importing eye bank and their unique ID number)
Age of donor
Cause of death
Death date and time
Enucleation or in-situ excision date and time
Preservation date and time
Slit lamp report
Specular microscopy (if done)
Name of enucleator/evaluator/technician
Name of surgeon receiving tissue
Recipient identification readily traceable to each unique graft number
(See Section M1.500)
Date, time, method of transportation
Utilization of tissue: i.e., surgical, research, training
Printed results of all EBAA required serologic screening tests
Microbiologic screening results if performed
Microbiologic reports of positive donor rim cultures from the receiving surgeon if reported
Adverse reactions if reported

M1.500 Recipient Follow-Up Information

1. Each eye bank shall retain recipient information from each using surgeon on each surgically used tissue. This information shall be obtained and retained by the distributing eye bank.
2. This information shall include the following:

Patient's name
Unique identification according to the following order of preference:
Social security number
Driver's license number
Hospital information number
Alien identification
Passport number
Age
Date of Birth
Diagnosis
Name of surgeon receiving transplanting tissue
Date of surgery
Location of surgery
Post-operative complications (tissue related)

3. Scleral tissue may be stocked at an institution only if it is for single patient use; the distributing eye bank must be notified of the recipient information when tissue is used and must be able to track the tissue.
4. Each eye bank must seek recipient follow-up information concerning possible adverse reactions on all tissue distributed between three and twelve months postoperatively.

N1.000 Amendments

These standards may be amended as required.

The Medical Advisory Board shall be charged with proposing amendments to these standards as medical technology, techniques and information require. A comment period may be provided prior to the intended effective date.

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